REMARKS

The Office Action dated October 26, 2005 has been carefully considered. It is noted that this Action has been made final even though a new theory of rejection has been advanced by the Examiner.

Claims 1-20, 23-26 and 28-29 have been rejected as obvious over Lederman Patent No. 6,210,318. It is respectfully submitted that patentably distinguish from Lederman for multiple reasons. First, these claims recite that a balloon (or chamber) is attached to a **shell**. Lederman **does not** disclose such a shell. Rather, Lederman discloses only a stent and a balloon which are **not** attached to each other. The "shell" recited in claim 1 cannot be considered to be the stent of Lederman because, as disclosed at page 5, lines 11-20 of the present application, shell 12 is separate and distinct from stent-graft 24. Thus, a separate and distinct element, shell 12, which is recited in claim 1, cannot be found in Lederman. This deficiency of Lederman has nothing to do with the issue raised by the Examiner (which will be discussed separately below) with regard to making two elements into one. In this regard, it is respectfully pointed out that claim 2, which is dependent upon claim 1, recites a stent, which stent is separate and distinct from the shell recited in claim 1. Thus, there is no element in Lederman which corresponds to the shell recited in claim 1 and in all of the other claims rejected as obvious over Lederman. This alone renders these claims patentable over Lederman who nowhere suggests the use of a shell in addition to a stent as a part of his system.

Furthermore, it is respectfully submitted that the Examiner's suggestion that the disclosure of Lederman permits the modification of the system disclosed therein, which comprises a balloon which is not attached to a stent, into a device in which the balloon is attached to the stent is directly contrary to the teaching of Lederman and does not at all involve converting a device which has two elements into a device comprising a single element by joining

those elements together. Rather, it is fundamental to the operation of Lederman that the balloon be "separately positionable with respect to said stent" as recited in claims 1-18 and 20-31 of Lederman, i.e., all of the system claims of Lederman. It is plain that Lederman desires freedom of movement between the balloon and the stent. In sharp contrast, claim 1 of the present application recites that the balloon is attached to a shell and claim 2 recites that the balloon is also attached to a stent. No such structure can be found in the system of Lederman because:

1. Lederman does not disclose a shell of any kind. Newly presented claim 30 makes this distinction more apparent by reciting the port in the shell and the tube attached to the port. No such structure is shown in the prior art.

2. Lederman does not disclose a balloon attached to a shell.

3. It is contrary to the teaching of Lederman for the balloon to be attached to a stent.

These fundamental structural differences also have functional importance. The attachment of the balloon to the shell reduces the amount of surface area of the balloon which is exposed to the blood which, in turn, reduces the possibility of blood clots forming on the surface of the balloon. Furthermore, the reason for refusing entry of the amendment filed January 28, 2006 does NOT APPLY TO CLAIM 2. Thus, claim 2 and the claims dependent on it are believed to be allowable.

In addition, claims 18-22, 26 and 27 recite a device and method wherein the inflation tube for the balloon is connected to the balloon by forming an aperture in the aorta or other artery after the balloon or stent is installed. Thus, this inflation tube will be a short length tube and not the long-length catheter disclosed by Lederman as being the inflation tube. The short-length tube installed in this manner is more conducive to permitting the heart assist device to remain in place for an extended period of time than the long-length catheter of Lederman.

Claims 21, 22 and 27 have been rejected as unpatentable over Lederman in view of Kiyota Patent No. 5,453,076. This rejection is misplaced because it focuses on the installation of a cardiac assist apparatus rather than the installation of an inflation tube. There is absolutely no disclosure in Lederman or Kiyota with regard to installation of an inflation tube by a sternotomy. In this regard, the remarks made above with regard to claims 21, 22 and 27 are applicable here. The Examiner's remark with regard to claim 22 and the Examiner's reference to column 9, lines 16-19 of Lederman is somewhat difficult to understand, but it has nothing to do with the installation of an inflation tube by means of a sternotomy or an aortotomy which is the method to which claim 22 is directed.

Furthermore, there is absolutely no suggestion in the art for combining Lederman and Kiyota. Lederman is directed to a system in which a balloon is installed intraluminally in a blood vessel whereas Kiyota is directed to a device which is installed extraluminally, i.e., on the outside of the heart. It would be hard to imagine to references less suitable for an attempted combination than Lederman and Kiyota. Thus, it is respectfully submitted that the combination of Lederman and Kiyota is impermissible and cannot stand.

It is respectfully submitted that this application has now been fully examined and that, for the reasons stated herein, the claims are patentably distinct from the prior art relied upon in the rejections of record. Thus, it is believed that the present application is in condition for allowance and a favorable action is respectfully solicited.

The Commissioner is authorized to charge Orrick's Deposit Account No. **15-0665** for any

fees required under 37 CFR §§ 1.16, 1.17 and 1.445 that are not covered, in whole or in part and credit any overpayments to said Deposit Account No. **15-0665**.

Respectfully submitted,

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